

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 18

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MARK A. DeROSCH, EDWARD A. DEUTSCH,
MARY M. DYSZLEWSKI and DENNIS L. NOSCO

Appeal No. 1997-2743
Application No. 08/442,252¹

ON BRIEF

Before WINTERS, ROBINSON and SCHEINER, Administrative Patent Judges.

SCHEINER, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the final rejection of claims 1, 3 through 12 and 15 through 18, the only claims pending in the application.

¹ Application for patent filed May 15, 1995.

Claims 1, 7, 8 and 17 are representative of the subject matter on appeal and read as follows:

1. A radiopharmaceutical kit comprising:

at least one ligand capable of bonding to a radioisotope during radiopharmaceutical solution formulation, wherein said ligand is selected from the group consisting of phosphines, arsines, thiols, thioethers, and isonitriles; and

a cyclic oligosaccharide as a stabilizing compound in an amount suitable to inhibit oxidation and/or volatilization of the ligand.

7. A radiopharmaceutical kit according to claim 1, wherein said cyclic oligosaccharide is a modified or unmodified cyclodextrin.

8. A radiopharmaceutical kit according to claim 7, wherein said modified or unmodified cyclodextrin is selected from the group consisting of " -cyclodextrin, \$-cyclodextrin, and (-cyclodextrin.

17. A radiopharmaceutical kit according to claim 1, wherein said radioisotope is technetium or rhenium.

The references relied on by the examiner are:

Feld et al. (Feld)	4,714,605	Dec. 22, 1987
Pitha	4,727,064	Feb. 23, 1988
Deutsch	5,002,754	Mar. 26, 1991
Woulfe et al. (Woulfe)	5,112,595	May 12, 1992

The claims stand rejected under 35 U.S.C. § 103 as follows:

I. Claims 1, 3 through 8 and 15 through 18 as unpatentable over Feld, Deutsch and Woulfe.

II. Claims 9 through 12 as unpatentable over Feld, Deutsch, Woulfe and Pitha.

We reverse both rejections.

DISCUSSION

Rejection I

Feld describes technetium^{99m}-dioxime complexes for imaging the myocardium, brain and hepatobiliary systems. The complexes “can be prepared by first combining pertechnenate ion (in the form of a salt) with a vicinal dioxime . . . and a halogen . . . by mixing a vicinal dioxime . . . , a source of halogen and a stabilizing agent.” Column 2, lines 15-20. The stabilizing agent, “a substance which is present during the preparation of the complex . . . to prevent or retard an unwanted alteration of the physical state of the complex and to increase the radiochemical purity of the labeled product,” can be “a primary, secondary or tertiary amine (e.g., mono-, di- or trialkylamines, arylamines, arylalkylamines, etc.), an amino alcohol, (e.g., alkanolamines), a diamine (e.g., alkanediamines, and amino acid or ester thereof (e.g., glycine or an alkyl ester thereof), or a salt of any of the above compounds, or “-, \$- or (-cyclodextrin.” Column 2, lines 41-52. Finally, Feld describes kits containing “a source of halogen, a dioxime . . . , a stabilizing agent and a reducing agent” (Column 3, lines 16-26) and also describes preparation of a Tc^{99m}-dioxime complex using a dioxime, (-cyclodextrin, sodium chloride, citric acid, a saturated aqueous solution of stannous pyrrophosphate and sodium pertechnetate (Example 10, Method III).

Deutsch describes a brain perfusion imaging agent comprising a technetium^{99m} (III/II) center surrounded by six ligating moieties, some of which can be phosphines. In

order “to establish an effective oxidation potential of the Tc(II) thus providing the necessary redox potential for in vivo oxidation,” four of the ligands “use phosphorous, arsenic, or nitrogen as ligating atoms,” while “[t]he remaining two ligands use sulfur or selenium to complex to the Tc center.” Abstract. Deutsch describes kits comprising phosphine salts bound to HCl, H₂SO₄, iron(II), copper(I) or zinc(II), but makes no mention of stabilizing agents.

Woulfe also describes Tc^{99m}-phosphine complexes, as well as kits comprising a phosphine salt bound to copper(I), and ascorbic acid as an anti-oxidant.

The examiner acknowledges that Feld does not disclose phosphine, arsine, thiol, thioether or isonitril ligands, but concludes that “it would have been obvious to employ in the [Deutsch] or [Woulfe] kits the cyclodextrin stabilizers disclosed by [Feld] since all three references teach Tc^{99m} labeled diagnostic ligands and kits,” while “[d]etermining optimum amounts of copper salt, ascorbic acid, ligand and sodium carbonate buffer would have amounted to optimization of reactant concentrations . . . and would have been routine experimentation for one of ordinary skill in the art.” Examiner’s Answer, paragraph 11(a). If we understand the rationale underlying the examiner’s rejection correctly, it is simply that all “Tc^{99m} labeled diagnostic ligands,” regardless of structure or other properties, are essentially interchangeable, and it would have been obvious for one skilled in the art to stabilize any Tc^{99m} ligand with any one of the many stabilizers disclosed by Feld.

We disagree. The examiner has merely established that individual elements of the claimed invention were known in the prior art: cyclodextrins were known stabilizers for Tc^{99m}-dioxime radiopharmaceutical complexes; and phosphines, like dioximes, were known ligands in Tc^{99m} radiopharmaceuticals. In our view, these facts alone do not provide a reason or suggestion to make the specific combination made by appellants.

As set forth in In re Kotzab, 217 F.3d 1365, 1369-70, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000):

A critical step in analyzing the patentability of claims pursuant to section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. [] Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one “to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher.” []

Most if not all inventions arise from a combination of old elements. [] Thus, every element of a claimed invention may often be found in the prior art. [] However, identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. [] Rather, to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant. [citations omitted]

In other words, “[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.” In re Fine, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988). “[T]here still must be evidence that ‘a skilled artisan, . . . with no knowledge of the claimed invention, would

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select the elements from the cited prior art references for combination in the manner claimed.” Ecolochem Inc. v. Southern California Edison, 227 F.3d 1361, 1375, 56 USPQ2d 1065, 1075-76 (Fed. Cir. 2000).

In our judgment, the only reason or suggestion to modify the teachings of the references in the manner proposed by the examiner comes from appellants' specification. Accordingly, on this record, we find that the examiner's burden of establishing a prima facie case of obviousness has not been met and the rejection of claims 1, 3 through 8 and 15 through 18 is reversed.

Rejection II

Pitha teaches that both unmodified and modified cyclodextrins (for example, hydroxypropyl cyclodextrin) are used to stabilize pharmaceutical compositions, but does nothing to remedy the underlying deficiency in the examiner's proposed combination of Feld, Deutsch and Woulfe.

Accordingly, the rejection of claims 9 through 12 as unpatentable over Feld, Deutsch, Woulfe and Pitha is reversed as well.

REVERSED

Sherman D. Winters
Administrative Patent Judge

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